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Required Report - public distribution

Date: 7/15/2010

GAIN Report Number: NI1006

Nigeria

Biotechnology - GE Plants and Animals

Agricultural Biotechnology Report

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Report Highlights:

In February 2009, Nigeria's Biosafety bill was introduced to the National Assembly for consideration and passage into law. The bill has gone through first and second reading, public hearing, retreat and collation of report at the lower House and there are indications that if the current momentum is sustained the bill could be passed into law in the next one year. The bill leans heavily on the precautionary approach and requires certification and mandatory labeling for imports of all products of biotechnology. This could negatively impact the importation of products derived through agricultural biotechnology. In the meantime, Nigeria is currently conducting field trials for transgenic cow pea and cassava varieties.

Section I. Executive Summary:

Nigeria, Africa's most populous nation (148 million), is a food deficit country. Formally a net food exporter, Nigeria's subsistence agriculture can no longer supply the needs of its growing population. According to trade sources, Nigeria imported about \$3.4 billion worth of agricultural commodities in 2009. Nigeria is largely a bulk commodity market and imports wheat, soybean products, tallow, rice and high value products. In CY 2009, U.S. agricultural exports to Nigeria reached \$834 million, primarily wheat. Nigeria became the largest buyer of U.S. wheat in the world in 2009/10.

The Draft Nigeria National Biosafety Bill was presented to the National Assembly (Congress) in January 2009 as a privately sponsored bill. The bill has passed through the first and second readings, public hearing, retreat and collation of report at the lower House. This bill is expected to be passed at the lower House soon, after which it will be transmitted to the Senate Chamber. Government sources indicate that the Bill will be passed into law and ready for the President's signature by the first quarter of 2011. The Bill covers all modern biotechnology activities - genetically modified organisms and other products of modern biotechnology, including all germplasm. The stated overall objective of the draft Biosafety Bill is to provide a regulatory regime and guidance for the sustainable development of modern biotechnology, its application and safe use of Genetically Modified Organisms (GMOs) and the products thereof without prejudice and risk to public health, environmental health, national sovereignty, human dignity and fundamental human rights.

The process leading to the presentation of the bill has been extremely slow and it has been in the works since the 1990s, with the Federal Ministry of Environment providing the lead. Nigeria signed the Cartagena Protocol on Biosafety in 2000 and its instrument of ratification was signed by the President on November 30, 2002. The protocol came into force in September, 2003. Nevertheless, very little was done to create the needed regulatory environment. The enactment of biosafety laws in South Africa, Mali, Burkina Faso and Kenya bolstered Nigeria's interest to move the process forward.

Major stakeholders in the country have urged the National Assembly to expedite action on the bill in order for the country to benefit from the technology. Hon. Gbenga Makanjuola, Chairman House Committee on Agriculture who is a key supporter of the bill was recently quoted to have said that "the potentials of biotechnology are immense, as it can enhance food security, wealth creation and environmental sustainability". He further said that "the vision of Nigeria's biosafety is to ensure that the practice of modern biotechnology are undertaken within the scope of a regulatory system that will guarantee its safe application, protect Nigeria's biodiversity and minimize or eliminate its risk to human health and the environment, and that all hands must be on deck by relevant stakeholders, by lending support to biosafety in this country." .

The African Union has also developed a biosafety model law as part of the overall efforts to encourage member countries to adopt the technology. The Economic Community of West African States is also developing common biosafety regulation/laws for the sub-region. Risk assessment /management, proof of safety before approval and the equivalence of GMOs with their conventional equivalent, cost and environmental impact are some of the issues that make the common approach important.

Nigeria's biosafety bill calls for the establishment the Biosafety Department under the National Biodiversity Management Agency. The Department is expected to be the focal point and authority on Biosafety in the country.

According to the Federal Government of Nigeria, the Biosafety Bill aims to:

- Define modules of practice of modern biotechnology and the handling of its products (GMOs) to ensure safety to the environment and to human health.
- Guide different segments of society in contributing to safe application of modern biotechnology.
- Recognize the complex issues to be addressed by central authorities in the judicious application of modern biotechnology.
- Ensure that modern biotechnology activities and their products (GMOs) are safe for the environment and to human

health.

- Base the deliberate release of GMO on advance informed agreement
- Define responsibilities among designated bodies/institutions.
- Confer powers to authorize release of GMOs and practice of modern biotechnology activities.
- Confers power to carry out risk assessment/management
- Define offences and penalty for violation of the act
- Cover all genetically modified organisms/living modified organisms, products food/feed and processing.
- Cover socio-economic consideration in risk assessment and labeling of all GM products

The Biosafety Bill also defines penalties for not complying with its regulations, and failure to obtain approval or proper permits before importing or releasing GMOs into the environment carry the following stated penalties:

- Individuals can be fined 2.5 million Naira or imprisonment for a period not less than 5 years or both;
- Corporations would pay a fine of not less than 5 million Naira and the directors or officers of the body shall each be liable to a fine not less than 2.5 million Naira or imprisonment for a term not less than 5 years or to both such fine and imprisonment.
- False information results in the same penalty as failure to obtain approval.
- Obstruction results in a 2.5 million Naira fine or imprisonment for not less than 3 years or both.

The draft bill contains some clauses that could negatively impact the importation of products derived through agricultural biotechnology. Section 9 (functions of the national biosafety committee) mandates the committee to assess and recommend approval of applications submitted for the import/export, transfer, and transit of GMO products. In addition, Part V (Notification and Authorization) clearly states that importation/exportation and movement of GMO products requires prior approval from the biosafety agency (when established) or the ministry of environment. Also, the bill requires mandatory labeling of products derived through agricultural biotechnology.

Currently, two biotech crops are undergoing field trials in Nigeria: the Bt Cowpea and the Bio-cassava Plus. Bt Cowpea has undergone first successful trial and is about going for the second trial with concomitant backcrossing going on at the Institute for Agricultural Research, Zaria, while Bio-Cassava Plus is still undergoing the first trial at the National Root Crop Research Institute, Umudike. The transgenic cassava, christened "Super Cassava," which is fortified with vitamin A was developed at the Danforth Center. A contained/confined field trial of Africa Bio-fortified Sorghum (ABS) is also planned. It is expected, by the time these trials are completed, Nigeria would have had a biosafety law in place to commence commercialization.

The interim regulatory arrangements:

The following regulatory measures and documents are in place pending the enactment of the biosafety law:

- i. The use of Cartagena Protocol on Biosafety
- ii. The use of the Nigeria National Biosafety Guidelines to process biosafety applications,
- iii. Biosafety application form
- iv. Biosafety Containment Facilities Guidelines
- v. Any Institute that intends to practice modern biotechnology or deal on GMOs must seek accreditation of the Institute and certification of its Biosafety containment Facilities,
- vi. Review of biosafety application by National Biosafety Committee,
- vii. Guidelines for Confined Field Trials

- viii. Monitoring and Inspection Manuals
- ix. GMOs import/ship form.

Section II. Plant Biotechnology Trade and Production:

A. Commercial Production of Biotechnology Crops

Nigeria does not currently produce any biotechnology crops commercially. A recent meeting organized by the NABDA, recommended that Nigeria should commence the commercialization of GM crops starting with crops with high industrial uses.

B. Biotechnology Research Efforts

Capacity exists at the International Institute for Tropical Agriculture (IITA) and to some extent at the GON's Sheda Science and Technology Complex (SHESTCO), to conduct and apply biotechnology research. The Bio-cassava Plus undergoing trials was developed in United States by the Plant Danforth Center, Missouri, while the Cowpea was developed in Australia but in both cases with significant participation of Nigerian Scientists. There is however, a good work going on local modification of local variety of tomato, a successful transformation has been carried by a NABDA scientist using the facilities at IITA, Ibadan.

Sustained research using modern agricultural biotechnology methods in Nigeria is being conducted at the IITA. The institute is doing preliminary work on bio-engineered cowpea.

C. Biotechnology Crops under Development

There is no biotechnology crop under development in Nigeria that will be on the market in the coming year. With transgenic insect-resistant cotton now in commercial production in Burkina Faso, the NBDA has indicated strong interest in commercial production of GMOs crops, such as bioengineered cotton and the genetically modified water efficient corn as soon as the bill is passed into law.

D. Imports of Biotechnology Crops/Products

Officially, Nigeria does not import bioengineered products. However, agricultural products such as soybeans, soybean meal, soybean oil, corn and processed food are freely imported from the U.S., EU, Brazil and Argentina and may contain biotech ingredients.

E. Food Aid

Nigeria has been a food aid recipient in the past, with rice, soybean meal and skim milk powder having been monetized under USDA food aid programs. No issues have arisen as a result of biotechnology and food aid.

F. Production of Biotechnology Crops Developed Outside the United States

At present, Nigeria does not produce biotechnology crops.

Section III. Plant Biotechnology Policy:

A. Regulatory Framework for Agricultural Biotechnology

i). Responsible institutions involved in agricultural biotechnology in Nigeria:

- The **Federal Ministry of Environment** is the National Focal Point and the competent Authority for Biosafety in Nigeria. It is the regulating body for modern biotech activities e.g. provision of the bio- safety/regulation requirements for bringing into the country Genetically Modified Crops for testing and release. This Ministry is

the GON's liaison with the Secretariat of the Convention on Biological Biodiversity for administrative functions required under the Cartagena Protocol on Biosafety. The National Focal point is responsible for all correspondences with importers, exporters and applicants on movement of products of modern biotechnology. Pending the passage of the National Biosafety Bill, the Minister of Environment acts for the National Biosafety Agency (NBA).

- The **Federal Ministry of Agriculture** is in charge of formulating agricultural policy as it relates to biotechnology, promoting and facilitating agricultural activities, implementation of the policies and programs of agriculture. It houses all agricultural research institutes in the country.
- **National Biotechnology Development Agency (NABDA)** was established in 2001 in the Ministry of Science and Technology with the mandate for formulating biotechnology policy in Nigeria, acquiring, deploying, promoting and facilitating biotech activities for indigenous and self-reliant national growth. The agency is active in creating awareness for products of biotechnology. NBDA conducts regular workshops for the major stakeholders in biotechnology.
- GON's **Sheda Science and Technology Complex (SHESTCO)** is a center for research and training in the area of modern biotechnology. It has the mandate to domesticate technologies for the application of modern biotechnology in health, agriculture, and environment.
- **Universities** are involved in research and development aspect of agricultural biotechnology. Most of them have Institutional Biosafety Committees.

ii). Role and Membership of the Biosafety Committee (NBC)

The NBC serves as the Competent National Authority for biosafety in Nigeria. The NBC is responsible for the safe management of biotechnology activities, including research, development, introduction and the use of LMOs/GMOs. The Committee has 16 members drawn from the Ministries of Agriculture, Science & Technology, Environment, Commerce, Education, Health (NAFDAC), Industry, Foreign Affairs, Internal Affairs (Nigerian Customs Service), Justice, and NACCIMA/Organized Private Sector. The NBC will also include a Biologist, a Physical Scientist, a Social Scientist and a Representative of NGOs distinguished in environmental/conservation matters. The NBC is required to review all applications for the release of products of bioengineering and make recommendations to the Minister of Environment on whether or not to allow such products. The NBC oversees the implementation of the National Biotechnology Program, consistent with the Biosafety Law.

The NBC has also established National Biosafety Technical Sub-committees (NBTS) to focus on sectoral interests such as agriculture, health, industry and the environment. The sub-committees review proposals for research and recommend the conditions under which experiments should be conducted. They are to provide technical advice to the NBC and contribute to its functions in relation to contained use, field trials, release and placement on the market.

All applications for import, field trials, transit and contained use must be routed through the registrar of the NBA. The NBC will meet and direct the relevant NBTS to carry out risk assessment and ensure participation of all relevant stakeholders. Findings of the NBTS are submitted to the NBC. The NBC takes a decision, which is then conveyed to the applicant by the Registrar of the NBA. A license to carry out event is issued by the Registrar of NBA.

iii). Political factors

The Nigerian government appreciates the potential of biotechnology to improve agricultural productivity. The national biotechnology policy document states that the GON "supports biotechnology because of its immense potential to more rapidly contribute to sustainable food security and economic growth". Government's support for the development of the technology is anchored on the country's need to feed the teeming population with the challenges of global warming and the attendant climate change. The Federal Ministry of Agriculture supports the application of Biotechnology in Agriculture. This is demonstrated by the action of the Minister in setting up a Study Group to develop a strategy for the application of biotechnology in Agriculture. The Director General of the National Biotechnology Development Agency is

the chairman of the committee.

B. Approval of Biotechnology Crops

At present, no law exists to approve biotechnology crops for food, processing and feed.

C. Field Testing

The National Biosafety Committee has granted approval to the National Root Crops Research Institute, Umudike and Institute of Agricultural Research (IAR), Zaria to carry out Confined Field Trials on transgenic cassava and cowpea, respectively. The approval was based on the provisions of the National Biosafety Guidelines. The guidelines have a provision for field-testing bio-engineered crops.

i). The Maruca - Resistant Cowpea Field Trial at IAR Zaria

This biotech event was developed by CSIRO Plant Industry Laboratory at Canberra Australia. The trial is sited on the Research Farm of the Institute of Agricultural Research, Ahmadu Bello University, Zaria. The field trial is to evaluate transgenic events (lines) for their reaction to the legume pod boring insect, Maruca. A line will be considered resistant if it does not sustain damage by the insect. In addition, effect of environment, agronomic performance such as plant morphology, maturity and yield will be assessed. The trial will be replicated four times.

Current status:

- The Bt Cowpea has undergone the 1st successful Confined field trial from 8th August 2009 to January 2010 and is about undergoing the 2nd trial.
- A risk communication workshop was organized by Africa Agriculture Technology Foundation (AATF) and the Program for Biosafety Systems (PBS) 2009 in Nigeria with the main objective of equipping the principal Investigators (from Ghana, Burkina Faso and Nigeria), Trial Managers, Government Officials and Stakeholders on how to communicate about GMOs and risk management to different audiences.
- This project is funded by AATF, Nairobi and aided by USAID and other Donors

ii). The Transgenic Cassava field Trial at Umudike

The National Root Crop Research Institute, Umudike has received approval to conduct contained field trials of biotech cassava variety. The transgenic cassava, christened "Super Cassava," which is fortified with vitamin A was developed at the Danforth Center.

Current Status:

- It was established in October 2009 and is funded by the Bill & Melinda Gates Foundation
- It is presently undergoing the first field trial where the activity carried out on a daily basis is the taking of normal growth parameters.
- The actual trait of interest will be measured at harvest period.

National Biotechnology Development Agency (NABDA) is collaborating with the institutes in creating awareness among Nigerian cowpea and cassava clientele, while the Biosafety Office of the Federal Ministry of Environment ensures compliance to Nigerian Biosafety guidelines in the conduct of the trial

Internationally the (AATF) provides funding platform, planning, capacity building and linking with other donors such as the USAID; the Network for the Genetic Improvement of Cowpea in Africa leverages scientific input of members for planning and linkage, the (PBS) assists in regulatory compliance capacity building and advice.

D. Participation in Meetings of International Standard-Setting Organizations

Nigeria signed the convention on biosafety in 1992 and ratified the instrument in 1994, and was an active participant in the negotiations leading to the adoption of the Cartagena Protocol. Officials of Key biotech agencies such as the Federal Ministry of Environment and NABDA regularly attend meetings of international standard-setting bodies.

E. Stacked events

The NBC does not require additional approval for stacked events

F. Review and Approval Process for Biotech Products for Planting and Import

At present, no laws exist to approve biotech products for planting and imports. However, the National Biosafety Guidelines adopted by the GON in 2001 has provision for field-testing bio-engineered crops.

G. Coexistence

Nigeria's proposed biosafety bill is silent on co-coexistence. However, there are provisions for monitoring in the draft bill. The relevant portion of the bill states, "for the purpose of biosafety, monitoring shall be used as a tool to ensure that the concerns expressed by stakeholders are addressed, ensure compliance with the terms of approval, confirm claims and trace the fate of LMOs/GMOs".)

H. Labeling

The National Agency for Food and Drug Administration and Control (NAFDAC) is the GON's regulatory body responsible for food product manufacturing, importation, advertisement and distribution in Nigeria. The NAFDAC was established to protect and promote public health by ensuring the wholesomeness, quality, and safety of food and drugs consumed in Nigeria. NAFDAC regulations require food labeling to be informative and accurate. The minimum labeling requirements include net content, specifying essential ingredients in metric weight for solids, semi-solids and aerosols, and metric volume for liquids. Ingredients must be listed by their common names in order of their prominence by weight. The regulations are being strictly enforced, but they are not specific to products of biotechnology. The draft biosafety bill, however, requires the mandatory labeling of all products of agricultural biotechnology in order to protect "consumers right to know."

I. Biosafety Protocol

Nigeria signed the Cartagena Protocol on Biosafety in 2000 and its instrument of ratification was signed by the President on 30th November, 2002. The protocol came into force in September, 2003. Nigeria, having signed and ratified the protocol, is now under obligation to implement it. The implementation of the protocol is slow and has had no effect on trade.

J. Biotechnology-Related Trade Barriers

We are not aware of any biotechnology-related trade barriers affecting U.S. exports to Nigeria and products such as U.S. soybean meal have been imported without problems.

K. Pending Legislation

The Ministry of Environment has prepared a draft biosafety bill. The draft bill advocates mandatory labeling of all products of agricultural biotechnology to protect "consumers' right to know." If the bill were enforced once passed, it could affect exports of U.S. food products to Nigeria.

L. Technology Fees

Nigeria does not have any technology fees for bio-engineered crops; neither does it have legislation in place to collect such fees.

Section IV. Plant Biotechnology Marketing Issues:

A. Market Acceptance

Generally, most Nigerians are not aware of products of modern agricultural biotechnology and the issues involved. Information and discussions on modern biotechnology have been undertaken largely among GON officials, scientists and researchers. Nigerian farmers and the general public will need to be educated about the technology.

Wheat importers in Nigeria favor the precautionary approach to biotechnology. They have learned about bio-engineered food products primarily from the U.S. - EU debate over biotechnology. Overall, Nigerian wheat importers have expressed the opinion that the U.S. should not introduce bio-engineered wheat into the market until all long-term health concerns are resolved. In MY 2009/10, Nigeria was the largest export market for U.S. wheat.

B. Focus Group Survey

The results of a focus group survey on the attitude of the public to biotechnology revealed that about 40 percent of respondents would not mind consuming bio-engineered food products. Many respondents especially among those with little education were ignorant of biotechnology and its potential usefulness. While some respondents did express concern about the long-term health effects of consuming such products, these concerns seem to be overshadowed by their basic need for affordable food. The survey also revealed a marked preference for biotech products developed locally to those that are imported.

Another national survey on public awareness of agricultural biotechnology in Nigeria was conducted in May 2004, preparatory to the launch of the Nigeria Agriculture and Biotechnology Project (NABP). Survey results suggest that the Nigerian public is only marginally aware of biotechnology. Those who are aware have heard something about biotechnology through stories in the news media. Most Nigerians do not have a clear understanding of biotechnology and many still confuse the technology with conventional breeding techniques. Nigerians are also not very knowledgeable about national and international policy issues relating to biotechnology. However, Nigerians are interested in the innovation and wish that it could be utilized to address the persisting problems of poverty in the country and one-third of respondents stated that they would be willing to eat genetically modified (GM) food if given the opportunity.

Following press statements by the AgAttache and a series of workshops conducted by USAID funded NAPB for civil servants, policy makers, legislators and for the members of the media, the level of awareness of issues relating to agricultural biotechnology has improved somewhat. Most newspaper articles are well balanced and are devoid of misconceptions about biotechnology.

A number of anti GMO NGOs are very active in the country.

Section V. Plant Biotechnology Capacity Building and Outreach:

A. U.S. Government or USDA Funded Outreach activities

Over the last five years, the USDA has helped to fund scientists to work on biotechnology at the IITA, under its technical assistance program. In addition, the AgAffairs Office in Lagos utilized the Cochran Fellowship Program to provide training in agricultural biotechnology in the U.S. for four Nigerian scientists during the same period. In 2005, AgAffairs Office in Lagos also nominated a journalist to participate in a biotechnology seminar sponsored by the US Grains Council.

In 2004, agricultural biotechnology in Nigeria received a boost with the launch of two linked initiatives funded by the USAID. These are the West African Biotechnology Network (WABNET) and the Nigeria Agricultural Biotechnology Project (NABP), implemented by CGIAR's International Institute for Tropical Agriculture (IITA), in close collaboration with Tuskegee University. The NABP was designed to assist Nigeria in building the framework for decision-making that will facilitate access to the opportunities biotechnology offers and will ensure the safe and effective application of this technology to improve agriculture. A key element of the project is to improve implementation of bio-safety regulations; and, enhance public knowledge and acceptance of biotechnology.

The project developed collaborative linkages with and provided facilities to some Nigerian universities/institutes to facilitate implementation; National Biotechnology Development Agency (NABDA) for biotech information dissemination; Sheda Science & Technology Complex (SHESTCO) for training of scientists; National Root Crops Research Institute

(NRCRI) for plant genetic transformation; Institute for Agricultural Research (IAR) for tissue culture and University of Agriculture, Abeokuta for advanced biotechnology training.

In early 2009, the USAID sponsored a study tour trip to the Philippines GM crop Farms for the House Committees members on Agriculture, Environment and Science and Technology to have a practical experience on GMOs and how they are being regulated as well as the legislation procedure. This trip was reported to be highly successful.

B. Country Specific Needs

FAS/Lagos proposes the implementation of two agricultural biotechnology workshops in collaboration with key stakeholders including the Department of Plant Sciences, ABU Zaria, National Biotech Development Agency and the Institute for Agricultural Research. One workshop each will be held at ABU Zaria and IITA in Ibadan. The primary objective of these workshops is to inform policy makers, regulators, producer groups, consumers and the media about the status of agricultural biotechnology in Nigeria. Other presenters would include a USDA land-grant university resource person who can discuss the status of agricultural biotechnology globally and explore potential avenues for future collaboration.

Institutional Capacity building

Local research institutions lack capacity in scientific DNA manipulation and laboratory management. Short-term training (2-4 weeks) through the Cochran Fellowship Program for two individuals from ABU Zaria and NRCRI would help strengthen local capacity. The training should be organized with US universities that have existing linkages with these institutes. They include UC Riverside and Purdue University. Both the outreach effort and the training should be implemented by USDA land-grant University.

Section VI. Animal Biotechnology:

There are no new technologies in use in Nigeria that go beyond biotechnology such as: the genetic engineering of agriculturally-relevant animals, animal cloning, plant that produce pharmaceuticals, etc.

Section VII. Author Defined:

REFERENCE MATERIALS

Nigeria Biosafety Guidelines 2001
Draft Nigeria Biosafety Bill 2006
Draft National Biosafety Framework
National Biosafety Policy

Copies of these documents are available in the AgAffairs office.

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